

CLAIMS

What is Claimed:

1. An isolated polynucleotide comprising a sequence selected from the group consisting of:
- (a) sequences provided in SEQ ID NOs:327-331, 337-341, and 377-390;
 - (b) complements of the sequences provided in SEQ ID NOs:327-331, 337-341, and 377-390;
 - (c) sequences consisting of at least 20 contiguous residues of a sequence provided in SEQ ID NOs:327-331, 337-341, and 377-390;
 - (d) sequences that hybridize to a sequence provided in SEQ ID NOs:327-331, 337-341, and 377-390, under moderately stringent conditions;
 - (e) sequences having at least 75% identity to a sequence of SEQ ID NOs:327-331, 337-341, and 377-390;
 - (f) sequences having at least 90% identity to a sequence of SEQ ID NOs:327-331, 337-341, and 377-390; and
 - (g) degenerate variants of a sequence provided in SEQ ID NOs:327-331, 337-341, and 377-390.
2. An isolated polypeptide comprising an amino acid sequence selected from the group consisting of:
- (a) sequences encoded by a polynucleotide of claim 1; and
 - (b) sequences having at least 70% identity to a sequence encoded by a polynucleotide of claim 1; and
 - (c) sequences having at least 90% identity to a sequence encoded by a polynucleotide of claim 1;

- (d) sequences set forth in SEQ ID NOs:241, 332-336, 342-346, 391-395, and 404-413;
- (e) sequences having at least 70% identity to a sequence set forth in SEQ ID NOs:241, 332-336, 342-346, 391-395, and 404-413; and
- (f) sequences having at least 90% identity to a sequence set forth in SEQ ID NOs:241, 332-336, 342-346, 391-395, and 404-413;

3. An expression vector comprising a polynucleotide of claim 1 operably linked to an expression control sequence.

4. A host cell transformed or transfected with an expression vector according to claim 3.

5. An isolated antibody, or antigen-binding fragment thereof, that specifically binds to a polypeptide of claim 2.

6. A method for detecting the presence of a cancer in a patient, comprising the steps of:

- (a) obtaining a biological sample from the patient;
- (b) contacting the biological sample with a binding agent that binds to a polypeptide of claim 2;
- (c) detecting in the sample an amount of polypeptide that binds to the binding agent; and
- (d) comparing the amount of polypeptide to a predetermined cut-off value and therefrom determining the presence of a cancer in the patient.

7. A fusion protein comprising at least one polypeptide according to claim 2.

8. An oligonucleotide that hybridizes to a sequence recited in SEQ ID NOs:327-331, 337-341, and 377-390 under moderately stringent conditions.

9. A method for stimulating and/or expanding T cells specific for a tumor protein, comprising contacting T cells with at least one component selected from the group consisting of:

- (a) polypeptides according to claim 2;
- (b) polynucleotides according to claim 1; and
- (c) antigen-presenting cells that express a polynucleotide according to claim

1,

under conditions and for a time sufficient to permit the stimulation and/or expansion of T cells.

10. An isolated T cell population, comprising T cells prepared according to the method of claim 9.

11. A composition comprising a first component selected from the group consisting of physiologically acceptable carriers and immunostimulants, and a second component selected from the group consisting of:

- (a) polypeptides according to claim 2;
- (b) polynucleotides according to claim 1;
- (c) antibodies according to claim 5;
- (d) fusion proteins according to claim 7;
- (e) T cell populations according to claim 10; and
- (f) antigen presenting cells that express a polypeptide according to claim 2.

12. A method for stimulating an immune response in a patient, comprising administering to the patient a composition of claim 11.

13. A method for the treatment of a cancer in a patient, comprising administering to the patient a composition of claim 11.

14. A method for determining the presence of a cancer in a patient, comprising the steps of:

- (a) obtaining a biological sample from the patient;
- (b) contacting the biological sample with an oligonucleotide according to claim 8;
- (c) detecting in the sample an amount of a polynucleotide that hybridizes to the oligonucleotide; and
- (d) compare the amount of polynucleotide that hybridizes to the oligonucleotide to a predetermined cut-off value, and therefrom determining the presence of the cancer in the patient.

15. A diagnostic kit comprising at least one oligonucleotide according to claim 8.

16. A diagnostic kit comprising at least one antibody according to claim 5 and a detection reagent, wherein the detection reagent comprises a reporter group.

17. A method for inhibiting the development of a cancer in a patient, comprising the steps of:

- (a) incubating CD4+ and/or CD8+ T cells isolated from a patient with at least one component selected from the group consisting of: (i) polypeptides according to claim 2; (ii) polynucleotides according to claim 1; and (iii) antigen presenting cells that express a polypeptide of claim 2, such that T cell proliferate;
- (b) administering to the patient an effective amount of the proliferated T cells, and thereby inhibiting the development of a cancer in the patient.

18. A composition comprising a WT1 polypeptide resuspended in a buffer comprising at least one sugar selected from the group consisting of trehalose, maltose, sucrose, fructose, and glucose, at a concentration of between about 7 and about 13 %.

19. The composition of claim 18 wherein said concentration is between about 8 and about 12%.

20. The composition of claim 18 wherein said concentration is about 10%.

21. A composition comprising a WT1 polypeptide resuspended in a buffer comprising at least 2 sugars selected from the group consisting of trehalose, maltose, sucrose, fructose, and glucose, at a concentration of between about 7 and about 13 %.

22. The composition of claim 21 wherein said concentration is between about 8 and about 12%.

23. The composition of claim 21 wherein said concentration is about 10%.

24. A composition comprising a WT1 polypeptide resuspended in a buffer comprising at least 3 sugars selected from the group consisting of trehalose, maltose, sucrose, fructose, and glucose, at a concentration of between about 7 and about 13 %.

25. The composition of claim 24 wherein said concentration is between about 8 and about 12%.

26. The composition of claim 24 wherein said concentration is about 10%.

27. A composition comprising a WT1 polypeptide resuspended in a buffer comprising:

- (a) at least one sugar selected from the group consisting of trehalose, maltose, sucrose, fructose, and glucose, at a concentration of between about 7 and about 13 %;
- (b) ethanolamine;
- (c) cysteine; and
- (d) Polysorbate-80.

28. The composition of claim 27 wherein said concentration is between about 8 and about 12%.

29. The composition of claim 27 wherein said concentration is about 10%.

30. A composition according to any one of claims 18-29 wherein the WT1 polypeptide comprises an Ra12-WT1 fusion polypeptide.

31. A composition comprising a WT1 polypeptide and MPL-SE.

32. The composition of claim 31 wherein the WT1 polypeptide comprises an Ra12-WT1 fusion polypeptide.

33. A composition comprising a WT1 polypeptide and Enhanzyn.

34. The composition of claim 33 wherein the WT1 polypeptide comprises an Ra12-WT1 fusion polypeptide.